Reply

To the Editors:

Thank you for giving us the opportunity to respond to Dr. Sandmann's letter. We thank him for his detailed critique of our article. Such discussion is to be encouraged when new methods of treatment are introduced, and especially when those new methods are as revolutionary as the endoluminal method of aneurysm repair. We agree with Dr. Sandmann that the long-term outcome of the endoluminal method are unknown. The medium-term outcome, however, is known. We have used the endoluminal method to treat abdominal aortic aneurysms in 106 patients, and we reported 32 of these who had their operation 2 years ago or more.[1] In addition, we have reported 47 patients who had their aneurysms repaired with the endoluminal method 1 year ago or more who were followed-up at 6-month intervals with contrast-enhanced computed tomographic scans.[2] The durability of the repair and the observed diminution in size of the aneurysm in these studies have encouraged us to continue with the method.

We also agree that close follow-up is mandatory after endoluminal abdominal aortic aneurysm repair. The patient who is the subject of the report is able to return for regular elective reviews but does not have access to emergency vascular surgical care. We were not as confident as Dr. Sandmann that dissection of the descending thoracic aorta was benign and stable, particularly with respect to the possibility of late complications developing if the entry point was not closed.

To clarify some other points raised in Dr. Sandmann's letter, we can confirm that the patient was normotensive, with normal renal arteries demonstrated on aortographic scans. The images that were published were selected to demonstrate the dissection and were not the best in the series to demonstrate the renal arteries. We can also confirm that the right kidney is indeed higher than the left and that all images are from the same patient.

We commend Dr Sandmann for his ability to repair similar thoracic dissections and fusiform aneurysms by open operation with minimal blood loss, expediency, and freedom from the anxiety of paraplegia. Regrettably, this has not been our experience.

Dr. Sandmann refers to the "pleasure" of performing open aortic replacement. We submit that the pleasure a surgeon derives from an operation should not be a factor in the choice of the operation. Rather, the focus should be on the patient's welfare. Endoluminal aneurysm repair, as with other minimally invasive procedures, aims to correct the pathologic process with a minimum of discomfort and disruption of the patient's life.

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REFERENCES

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2. May J, White GH, Yu W, Waugh R, Stephen MS, Harris JP. A prospective study of anatomico-pathological changes in AAA following endoluminal repair. Eur J Vasc Endovasc Surg. In press.

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Regarding "Thrombolysis or peripheral arterial surgery: Phase I results"

To the Editors:

In the article "Thrombolysis or peripheral arterial surgery: Phase I results," Drs. Ouriel, Veith, and Sasahara, on behalf of the TOPAS Investigators (J Vasc Surg 1996; 23:64-75), recommended that an initial recombinant urokinase dose of 4000 IU/min would be safe and efficacious (capable of producing the desired result) in the treatment of acute leg ischemia. Review of the article shows that all of the recommended doses were efficacious, but the authors believed that the 4000 IU/min was most efficacious. In making that decision, however, the surgeon must consider the cost of therapy, the cost of complications, and failed therapy. One method of evaluation is to consider the cost of standard urokinase in these treatment regimens.

The cost of urokinase at our hospital is $344 per 250,000 IU. Therefore, a 24-hour cost (average infusion time = 23 hours) of urokinase for the 2000 IU/min regimen is $3848, for the 4000 IU/min regimen is $4489, and for the 6000 IU/min regimen is $5,130.

Several assumptions must be made to evaluate the data from the article to give comparative costs. All groups were demographically similar and had definitive surgery. Group comparisons showed similar distribution of operations, making operative and hospitalization costs similar. If one assumes that the complication of bleeding added 2 days to the hospitalization at a cost of $2000 per day, then each bleeding complication cost $4000. Therefore, the only variable in cost comparisons is the bleeding rate and the cost of that bleeding. This must be considered in the failure arm of any evaluation.

This information can then be put into decision-tree analysis, with arms showing the cost of success and the cost of failure. Then, the most cost-efficient treatment can be selected. A decision tree for urokinase therapy is shown in Fig. 1.

The cost of urokinase therapy at an initial dose of 2000 IU/min totals $4368. The 4000 IU/min regimen shows a cost of $4569, and the 6000 IU/min dose a cost of $5770. Given the assumptions listed above and the similar thrombolysis effect (complete thrombolysis, 67% vs 71%), an initial urokinase dose of 2000 IU/min is the most cost-efficient choice. Although the difference between the 2000 IU/min regimen and the 4000 IU/min regimen is only

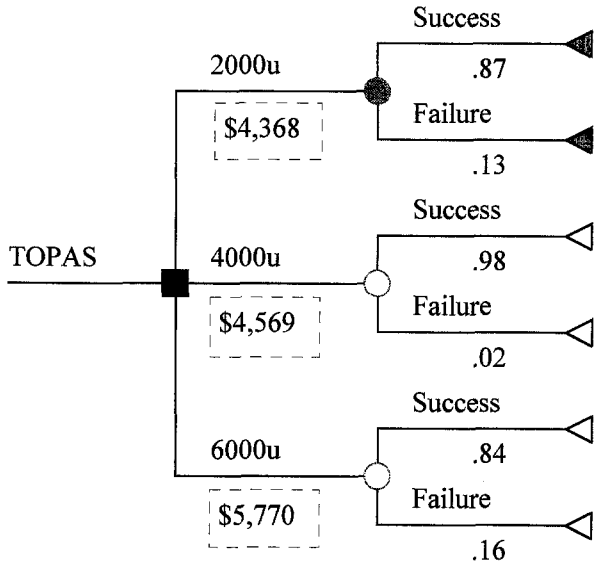

Fig. 1. Decision tree for urokinase therapy.

$200 per patient, logic dictates that in time the bleeding complications should be less with a lesser dose of urokinase. If that lessening occurs, then this cost analysis becomes even more practical.

In future TOPAS articles, I would encourage the authors to include costs or charges, or even a decision analysis, so that we may all have more data to examine urokinase therapy in this age of cost containment.

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Reply

To the Editors:

Dr. Weiland has brought forth some interesting comments with regard to an economic analysis of the TOPAS phase I data. His principles are instructive in reiterating the necessity of a rational decision-tree analysis for cost-benefit assessment. Dr. Weiland's analysis, however, uses only bleeding complications as the measure with which to gauge success or failure of the procedure. Clearly, amputation and patient mortality rates overshadow bleeding as the most appropriate primary endpoints of success.

The 4000 IU/min urokinase dose was chosen by the investigators as the most appropriate dose to continue phase II after a review of all the primary and secondary endpoints available after a short period of follow-up. Economic outcome was not considered in this decision. Nevertheless, the lack of a difference in the length of hospital stay, concurrent with trends toward improved 1-year amputation-free survival rates in the 4000 IU/min group ($p = 0.07$) suggests that the investigators made an appropriate decision in choosing the intermediate dose. A formal cost-benefit analysis is now underway, and the investigators hope to have the opportunity to report this data in the near future.

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